UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: BIOZORB DEVICE PRODUCTS LIABILITY LITIGATION *This Document Relates to: Kimberly Taylor in Case No. 1:23-cv-10260 and Plaintiff Beth Deuel in Case No. 1:23-cv-10579*	**Case No. 1:22-cv-11895-ADB**

DEFENDANT HOLOGIC, INC.'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT

Plaintiffs Kimberly Taylor and Beth Deuel allege that they developed pain and other injuries as a result of the BioZorb, a medical device that was implanted during surgeries to remove cancerous tissue. They assert various causes of action against Defendant Hologic, Inc. ("Hologic"), including negligent design, negligent failure to warn, and breach of the implied warranty of merchantability. The Court should grant summary judgment in favor of Hologic on all of these claims because Plaintiffs have no admissible expert evidence that BioZorb can cause the types injuries they claim, let alone that the device caused their specific injuries. Without this required evidence, all of Plaintiffs' claims fail.

BACKGROUND

Plaintiffs Taylor and Deuel are two of several plaintiffs that have filed product liability claims relating to the BioZorb implantable marker, a medical device manufactured by Hologic. *See* Def's Mot. to Exclude Dr. Jones (ECF No. 275), at 2-7. On February 26, 2024, in furtherance of the effective and efficient case management of the above-captioned litigation, the Court entered the Parties' jointly-proposed bellwether plan. ECF No. 84 (the "Bellwether Order"). Among other things, the Bellwether Order established a system pursuant to which the Parties selected four

plaintiffs from the first five cases for bellwether trials. *See generally id*. Those plaintiffs are Kimberly Taylor, Beth Deuel, Cynthia Kresch, and Pamela Gibson. *See* ECF No. 201 at 1-2. Plaintiff Taylor's trial will take place first, commencing on September 8, 2025, followed by Plaintiff Deuel's trial, which will commence on January 20, 2026. *See* ECF No. 208; ECF No. 214 at ¶ 2. On January 31, 2025, the Court entered a scheduling order setting certain pre-trial deadlines, including deadlines for (1) serving expert reports for generic experts (including liability experts and any experts giving "general" causation opinions) in all four bellwether cases; (2) serving case-specific expert reports for Plaintiffs Taylor and Deuel; (3) filing *Daubert* motions for generic experts and case-specific experts for Plaintiffs Taylor and Deuel; and (4) filing summary judgment motions for Plaintiff Taylor.[1] *See* ECF No. 218.

Plaintiff Taylor filed her claims in January 2023, alleging pain, a palpable mass, and other injuries which she attributes to the BioZorb. *See* SUF ¶ 1; Wiesner Decl. Exs. 1, 2. Her complaint asserts four causes of action: Negligence: Failure to Warn (Count I), Negligence: Design Defect (Count II), Breach of Implied Warranty (Count III), and Negligence (Count IV).[2] *See* Wiesner Decl. Ex. 2 at ¶¶ 44-89.

Plaintiff Deuel filed her claims in March 2023, alleging pain, a palpable mass, and other injuries which she attributes to the BioZorb. *See* SUF ¶ 2; Wiesner Decl. Exs. 3, 4. Her complaint asserted four causes of action: Negligence: Failure to Warn (Count I), Negligence: Design Defect (Count II), Breach of Implied Warranty (Count III), and Negligence (Count IV). *See* Wiesner

[1] The Court has not yet set a deadline for filing motions for summary judgment for Plaintiff Deuel. Hologic accordingly reserves the right to file a further summary judgment motion as to Plaintiff Deuel at a later date.

[2] On May 30, 2025, Plaintiff Taylor filed a motion to amend her complaint. *See* ECF No. 263. The proposed amended complaint would add two additional causes of action, for strict liability design defect and strict liability failure to warn. *See id*. at 263-1. As of the date of this filing, this motion remains pending.

Decl. Ex. 4 at ¶¶ 48-92. On February 3, 2025, the Court granted Hologic's intermediate motion for summary judgment in part, and dismissed Plaintiff Deuel's negligent failure to warn claim (Count I), as well as her implied warranty and general negligence claims (Counts III and IV) to the extent those claims are premised on a failure to warn. *Id*. Ex. 5 at 10-11. Accordingly, Plaintiff Deuel's only remaining claims are those that sound in negligent design. *See id*.

LEGAL STANDARD

Summary judgment is proper where "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a)). "Summary judgment is not a 'disfavored procedural shortcut.'" *Caputo v. Bos. Edison Co.*, 924 F.2d 11, 12 (1st Cir. 1991) (quoting *Celotex Corp. v. Vatrett*, 477 U.S. 317, 327 (1986)). Rather, it is an integral part of the Federal Rules as a whole, which are designed to secure the just, speedy and inexpensive determination of every action." *Celotex Corp.*, 477 U.S. at 327 (quoting Fed. R. Civ. P. 1). To avert a properly supported summary judgment motion, the non-moving party must "must adduce specific, provable facts which establish that there is a triable issue;" it cannot "rest upon mere allegations" or evidence that is "merely colorable or … not significantly probative." *Febus-Rodriguez v. Betancourt-Lebron*, 14 F.3d 87, 91 (1st Cir. 1994). Put differently, "the mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no *genuine* issue of *material* fact." *Anderson v. Liberty Lobby, Inc*., 477 U.S. 242, 247–48 (1986).

ARGUMENT

I. PLAINTIFFS CANNOT SHOW THAT BIOZORB WAS A LEGAL CAUSE OF THEIR INJURIES

The Court has already determined that "[u]nder Massachusetts conflict-of-laws rules, Michigan law governs Deuel's claims." Wiesner Decl. Ex. 5 at 7. This is because Plaintiff Deuel

"testified in her deposition [that] she has been a resident of Michigan for her entire life, was implanted with the BioZorb device there, and suffered her resulting injuries there." *Id*. (internal citations omitted). New York substantive law applies to Plaintiff Taylor's claims for much the same reasons: Plaintiff Taylor was implanted with the BioZorb in New York, where she currently resides and resided at the time of her partial mastectomy. *See id*.; *In re BioZorb Device Prod. Liab. Litig*., Nos. 22-cv-11895, 22-cv-12194, 2024 WL 4309413, at *8–9 (D. Mass. Sept. 26, 2024); Wiesner Decl. Ex. 2 at ¶ 21; Wiesner Decl. Ex. 6 (Taylor Dep.) at 41:21-24; 71:22-72:6; Wiesner Decl. Ex. 7.

In New York and Michigan, causation is a required element in every product liability personal injury action. *See, e.g.*, M.C.L. 600.2945(h); *Thomas v. C.R. Bard, Inc.*, No. 20-cv-2738, 2022 WL 16748753, at *4 (S.D.N.Y. Nov. 7, 2022) (collecting cases). In cases such as this, the causation inquiry consists of two parts, ***both*** of which are required to get to a jury: whether the product in question is capable of causing a particular injury or condition in the general population (*i.e.,*, general causation), and, if so, whether it actually caused the plaintiff's specific harm (*i.e.*, specific causation). *See, e.g.*, *In re Rezulin Prods.*, No. MDL 1348, Civ 2843, 2004 WL 2884327, at *2 (S.D.N.Y. Dec. 10, 2004) ("Causation in toxic tort cases has two components: general and specific … A plaintiff must establish both in order to prevail."); *Thomas*, 2022 WL 16748753 at *4 ("[P]laintiffs in product liability cases generally must offer admissible expert testimony regarding both general causation … and specific causation") (internal quotations and citation omitted); *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 881 (10th Cir. 2005) ("in silicone breast implant litigation, plaintiffs must show both general and specific causation"); *Thompson v. Orkin, LLC*, No. 20-cv-13085, 2025 WL 18639, at *5 (E.D. Mich. Jan. 2, 2025) ("Under Michigan law, in a toxic tort case, the plaintiff must present admissible general-causation and specific-

causation evidence through proof that the toxic substance was capable of causing and did cause the plaintiff's alleged injury"); *see also Powell-Murphy v. Revitalizing Auto Communities Env't Response*, 964 N.W.2d 50, 58-60 (Mich. App. 2020) (citing *Lowery v. Enbridge Limited P'ship.* 898 N.W.2d 906, 907-24 (Mich. 2017) (Markman, C.J., concurring)).

Where, as here, that causal link is beyond the knowledge or expertise of a layperson, expert testimony is required to establish causation. *See, e.g.*, *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 268 (2d Cir. 2002) (under New York law, "to establish causation, [plaintiffs] must offer admissible expert testimony regarding both general causation … and specific causation"); *In re Dow Corning Corp.*, 541 B.R. 643, 654 (E.D. Mich. 2015) (in Michigan product liability actions, "expert testimony is indispensable to prove causation where 'it is to the scientific community that the law must look for the answer'" (citation omitted)), *aff'd sub nom. Ezra v. DCC Litig. Facility, Inc.,* 667 Fed. Appx. 538 (6th Cir. 2016); *In re Onglyza & Kombiglyze Prods. Liab. Litig.*, 93 F.4th 339, 348–49 (6th Cir. 2024) ("all jurisdictions require expert testimony to show general causation … where the issues are medically complex and outside common knowledge and lay experience").

Defendants are entitled to summary judgment where plaintiffs fail to adduce required expert evidence on either general or specific causation. Indeed, courts presiding over MDLs involving medical devices, pharmaceutical products, or exposure to toxic substances routinely grant summary judgment to defendants where plaintiffs' causation experts are excluded under *Daubert*. *See, e.g.*, *In re Onglyza*, 93 F.4th at 349 (affirming entry of summary judgment in favor of defendants where plaintiffs' general causation expert was excluded: "all jurisdictions require expert testimony to show general causation in complex medical cases such as this MDL. Dr. Goyal's exclusion warranted the district court's grant of summary judgment to defendants"); *In re*

Mirena IUS Levonorgestrel-Related Prods. Liab. Litig. (No. II), 982 F.3d 113, 124–26 (2d Cir. 2020) (similar); *In re Zoloft Prods. Liab. Litig.*, 176 F. Supp. 3d 483, 501 (E.D. Pa. 2016) (entering summary judgment against hundreds of plaintiffs after excluding their general causation experts under *Daubert*), *aff'd sub nom. In re Zoloft Prods. Liab. Litig.*, 858 F.3d 787 (3d Cir. 2017); *In re Acetaminophen Prods. Liab. Litig.*, No. 22-md-3043, 2024 WL 3874183, at *3 (S.D.N.Y. Aug. 20, 2024) (similar); *In re Bausch & Lomb*, 693 F. Supp. 2d 515, 518–19 (D.S.C. 2010) (similar), *aff'd sub nom. Fernandez-Pineiro v. Bausch & Lomb, Inc*., 429 Fed. Appx. 249 (4th Cir. 2011); *In re Zantac (Ranitidine) Prods. Liab. Litig.*, 644 F. Supp. 3d 1075, 1286 (S.D. Fla. 2022) (similar).

Plaintiffs here have failed to proffer admissible expert evidence on both general and specific causation. SUF ¶¶ 3-7. They have presented three experts who purport to give these medical causation opinions: Dr. Scott Guelcher (a chemical engineer), Dr. Niamey Wilson (a breast surgeon), and Dr. Guy Jones (a radiation oncologist). *See* SUF ¶¶ 3-5; Wiesner Decl. Exs. 8-12. But for the reasons explained in Hologic's separate *Daubert* motions, those medical causation opinions are unreliable or otherwise inadmissible.[3] Without this required proof, Plaintiffs cannot prevail on any of their claims and summary judgment should be granted. *See, e.g.*, *Heckstall v. Pincus*, 19 A.D.3d 203, 204–05 (N.Y. 2005) (directing judgment in favor of manufacturer defendant on failure to warn, design defect, and breach of warranty claims where plaintiff "failed to submit sufficient [expert] evidence as to either general or specific causation"); *Amorgianos*, 303 F.3d at 270-72 (affirming summary judgment to defendant in product liability case due to the "absence of any expert evidence as to general causation"); *Thomas*, 2022 WL 16748753, at *5–6 (entering summary judgment against plaintiff in product liability case for lack

[3] *See* Def's Mot. to Exclude Dr. Jones (ECF No. 275). Pursuant to the Court's May 30, 2025 Order, Hologic will file its *Daubert* motions to exclude Dr. Wilson and Dr. Guelcher on June 13, 2025, as both Dr. Wilson and Dr. Guelcher served rebuttal reports. ECF No. 262.

of expert evidence on general and specific causation); *In re Dow Corning Corp.*, 541 B.R. at 654-55 (entering summary judgment against plaintiff in breast implant product liability case after excluding her causation experts under *Daubert*); *Thompson v. Orkin, LLC*, No. 1:20-CV-13085-TGB-PTM, 2025 WL 595160, at *8 (E.D. Mich. Feb. 24, 2025) (entering summary judgment against plaintiffs on claim that defendant's negligence caused their depression after excluding plaintiffs' causation experts as to that injury); *In re Roundup Prods. Liab. Litig.*, No. 16-MD-02741-VC, 2022 WL 17332799, at *1 (N.D. Cal. Nov. 29, 2022) (applying Michigan law) (granting summary judgment where plaintiff failed to designate a specific causation expert because "[w]ithout expert testimony on causation, a jury can only speculate whether Roundup caused her illness.").[4]

CONCLUSION

For the foregoing reasons, Hologic respectfully requests that the Court grant its motion for summary judgment and dismiss Plaintiffs' remaining claims in their entirety.

Dated: June 6, 2025

Respectfully submitted,

HOLOGIC, INC.,
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[4] To be clear, Hologic believes that Plaintiffs' experts opinions on ***both*** general causation and specific causation are inadmissible. However, it would be sufficient for entry of summary judgment if the Court finds that Plaintiffs have no admissible general causation opinions ***or*** no admissible specific cause opinions, since Plaintiffs are obligated to prove both strands of causation. *See* discussion *supra* at 4-6.

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the CM/ECF system will be sent electronically to the registered participants as identified on the NEF (NEF) and paper copies will be sent to those indicated as non-registered participants on June 6, 2025.

/s/ Pietro A. Conte
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